

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

**UNITED STATES OF AMERICA EX REL.
CRYSTAL DERRICK,**

Plaintiff-Relator,

v.

**ROCHE DIAGNOSTICS CORP.; ROCHE
DIABETES CARE, INC.; ROCHE HOLDINGS
AG; HUMANA, INC.; AND HUMANA
PHARMACY, INC.,**

Defendants.

Case No. 14-cv-04601

JURY TRIAL DEMANDED

**SECOND AMENDED
COMPLAINT**

Plaintiff and Relator Crystal Derrick (“Relator”), by and through her attorneys, brings this action on behalf of the United States of America pursuant to the *qui tam* provisions of the Federal False Claims Act (“FCA”), 31 U.S.C. §§ 3729-3733, against Roche Diagnostics Corp., Roche Diabetes Care, Inc., Roche Holdings AG (collectively, “Roche”) and Humana, Inc. and Humana Pharmacy, Inc. (“Humana Pharmacy”) (collectively, “Humana”) (collectively with Roche, “Defendants”) to recover all damages, penalties, and other remedies provided by the False Claims Act. In support thereof, Relator alleges as follows:

I. NATURE OF THE CASE

1. Relator brings this action to recover for false claims resulting from Defendant Roche’s illegal cancellation of debt owed to it by the managed healthcare company, Defendant Humana, with the intent to induce Humana to list Roche’s products on its formulary. Defendants’ unlawful scheme violated the federal Anti-Kickback Statute (“AKS”), 42 U.S.C. § 1320a-7b(b),

and caused false or fraudulent claims to be submitted for payment by Government health-care programs.

2. Relator learned during her tenure at Roche that Defendants have violated and continue to violate the FCA by engaging in an illegal kickback scheme to secure Roche's access to Humana's formularies, and then fraudulently charge Government healthcare programs, including Medicare, for tainted purchases from those formularies.

3. When Relator raised concerns about these practices with corporate management, Roche terminated her employment, in retaliation for her reporting a fraud.

II. THE PARTIES

A. Plaintiff-Relator

4. Relator and Original Source **Crystal Derrick** is a resident of Dayton, Ohio. She was a National Account Manager in the Diabetes Division of Roche Diagnostics Corp. from October 15, 2012 through December 10, 2013. Relator personally witnessed the internal discussions at Roche that led to its decision to forgive Humana's debt in order to secure access to its formularies. Consequently, Relator and Original Source Derrick has direct and independent knowledge of Defendants' false claims to the Government, as alleged herein.

B. Defendants

5. Defendant **Roche Diagnostics Corp.** is a corporation organized under the laws of the State of Indiana, with its principal place of business at 9115 Hague Road, Indianapolis, Indiana 46250. Roche Diagnostics Corp. has five principal business divisions, including Roche Diabetes.

6. Defendant **Roche Diabetes Care, Inc.** is a corporation organized under the laws of the State of Delaware, with its principal place of business at 9115 Hague Road, Indianapolis, Indiana 46250. Roche Diagnostics Corp. included Roche's U.S. commercial diabetes business

until November 2015, when the U.S. commercial diabetes business was transferred to a separate legal entity, Roche Diabetes Care, Inc. Roche Diabetes Care, Inc. is engaged in the business of manufacturing and marketing blood glucose test strips.

7. **Defendant Roche Holding AG** (“Roche AG”) is a for-profit healthcare company located in Basel, Switzerland. The Company’s operating businesses are organized into two divisions: Pharmaceuticals and Diagnostics. The Pharmaceuticals Division consists of two business segments: Roche Pharmaceuticals and Chugai. The Diagnostics Division consists of four business areas: Diabetes Care, Molecular Diagnostics, Professional Diagnostics and Tissue Diagnostics. Roche AG is the ultimate parent company of Roche Diagnostics Corp. and Roche Diabetes Care, Inc.

8. Defendant **Humana, Inc.** is a for-profit health insurance company based in Louisville, Kentucky. Humana enters into contracts with the government to provide Medicare Advantage and Part D managed healthcare coverage to customers. It also provides other healthcare services, including operation of a mail-order pharmacy referred to as “Humana Pharmacy.” Humana, Inc. is one of the largest Medicare Advantage providers in the country, with over three million members. In 2016, Humana, Inc. received \$31,863,000,000 in premiums and services revenue under individual Medicare Advantage contracts. Medicare accounts for approximately 75% of Humana Inc.’s total premium and service revenue.

9. Defendant **Humana Pharmacy, Inc.** (“Humana Pharmacy”) is a Delaware Corporation with its principal place of business in Phoenix, Arizona. During relevant periods, Humana Pharmacy operated a mail-order pharmacy referred to as “RightSource.” Humana Pharmacy provides mail-order pharmacy services to customers nationwide including, without limitation, customers enrolled in Humana’s Medicare Advantage program.

III. JURISDICTION AND VENUE

10. The Court has subject-matter jurisdiction over this action under 31 U.S.C. § 3732(a) as well as federal-question jurisdiction under 28 U.S.C. § 1331.

11. The Court has personal jurisdiction over Defendants under 31 U.S.C. § 3732(a), because the False Claims Act authorizes nationwide service of process and the Defendants can be found, reside, or transact business within the District.

12. Venue is proper in this District under 31 U.S.C. § 3732(a), because the Defendants can be found, reside, or transact business within the District, and many of the acts forming the basis of this action occurred within the District.

13. In conformity with 31 U.S.C. § 3730(b)(2), Relator has served a written disclosure of all material evidence and information in her possession on the United States Attorney General and the United States Attorney for this District.

14. There has been no statutorily relevant public disclosure of the “allegations or transactions” in this Complaint to Relator’s knowledge. *See* 31 U.S.C. § 3730(e)(4). Assuming there had been such a disclosure, Relator is an “original source” under the FCA. *Id.*

IV. STATUTORY AND REGULATORY BACKGROUND

A. The False Claims Act

15. The FCA holds liable anyone who “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval” by the United States, 31 U.S.C. § 3729(a)(1)(A), or who “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.” *Id.* § 3729(a)(1)(B). Those who violate the FCA are liable for civil penalties of at least \$5,500 and up to \$11,000 per violation, three times the damages sustained by the Government, and litigation costs. *See id.* § 3729(a)(1), (3).

16. The FCA provides that a person with knowledge of false or fraudulent claims or records presented to the United States may bring a private (*qui tam*) action on behalf of both the person (the “relator”) and the Government, and may share in any recovery of money by or on behalf of the United States in the action. A prevailing relator is also entitled to attorneys’ fees, costs, and expenses. *See* 31 U.S.C. § 3730(d).

B. The Anti-Kickback Statute

17. The Anti-Kickback Statute (“AKS”) makes it a felony to, *inter alia*, knowingly pay or accept remuneration to induce anyone “to refer an individual to a person for the furnishing[,] or arranging for the furnishing[,] of any item or service for which payment may be made in whole or in part under a Federal health care program.” 42 U.S.C. § 1320a-7b(b)(2)(A). The AKS thus holds liable both the person paying and the person accepting a kickback.

18. Unlawful remuneration includes any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind, for referrals, subject to specific exclusions. 42 U.S.C. § 1395nn(h)(1)(B); 42 C.F.R. § 411.351.

19. Unlawful remuneration likewise includes that which is provided: “(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.” 42 USCS § 1320a-7b.

20. Compliance with the AKS is a condition of payment by Federal healthcare programs, including Medicare, and a claim for reimbursement from such programs for items or services furnished or arranged in return for a kickback is a false claim under the FCA. *See* 42

U.S.C. § 1320(a)-7b(g); *United States v. Omnicare, Inc.*, No. 07-cv-05777, 2013 U.S. Dist. LEXIS 102543, *27 (N.D. Ill. July 23, 2013).

21. A company's failure to collect money that is owed to it by an entity from which the company intends to induce such reimbursement from Federal healthcare programs is considered remuneration under the AKS. *United States ex rel. Fontanive v. Caris Life Sciences, Inc.*, No. 3:10-cv-02237-P (N.D. Tex. Oct. 23, 2013); *United States ex rel. Ruscher v. Omnicare*, No. 4:08-cv-03396, 2014 U.S. Dist. LEXIS 79885, at *23-25 (S.D. Tex. Jun. 12, 2014).

22. A 2010 clarifying amendment of the AKS provides that “a claim [to a Federal healthcare program] that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of” the False Claims Act. Patient Protection and Affordable Care Act, Pub. L. 111–148, § 6402, 124 Stat. 468, 759 (2010), *codified at* 42 U.S.C. § 1320a-7b(g).

23. If even one purpose of remuneration is to induce referrals for covered items or services, such payment of remuneration violates the AKS. In such circumstances, claims for Federal reimbursement arising from the referrals violate the FCA, even if other, legitimate purposes may be present.

C. The Medicare Program and Prescription Drug Formulary Coverage

1. Medicare Part B

24. Medicare Part B is a fee-for-service health insurance program that covers certain doctors' services, hospital outpatient services, and durable medical equipment (DME) considered medically necessary to treat a disease or condition. Medicare Part B's coverage of DME includes coverage of equipment necessary for glucose monitoring.

25. In July, 2013, CMS announced that Medicare Part B would utilize private mail

order pharmacies to deliver medical equipment for diabetes management to beneficiaries.

2. The Medicare Advantage Program

26. Medicare Part C (“Medicare Advantage”) is a federal program that contracts with private insurance companies called Medicare Advantage Organizations (“MAOs” or “MA organization”) to provide Medicare Part A and B benefits to Medicare beneficiaries. The plans must at a minimum cover all services covered by Medicare Part A and B, with the exception of hospice care. The federal government compensates the private insurance companies for their delivery of these services at a capitated rate.

27. Every year, Medicare Advantage Organizations submit bids to the Center for Medicare Services, offering to provide their services for a specified amount per member per month (PMPM). The bids report the costs of providing benefits for the previous calendar year; actual allowed per member per month (PMPM) cost, unit cost, and utilization by service type (for example, inpatient, outpatient, etc.); cost sharing; and net costs. MAOs must also report actual enrollment and revenue, as well as expenses for claims, administration, and gain/loss margin.

28. CMS regulations state that “in order to qualify as an MA organization, enroll beneficiaries in any MA plans it offers, and be paid on behalf of Medicare beneficiaries enrolled in those plans, an MA organization must enter into a contract with CMS.” 42 C.F.R. § 422.503 (a).

29. “The contract between the MA organization and CMS must contain the following provisions: . . . Requirements of other laws and regulations. The MA organization agrees to comply with—(1) Federal laws and regulations designed to prevent or ameliorate fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. 3729 et. seq.), and the Anti-Kickback statute (section 1128B(b) of the Act).” 42 C.F.R. § 422.504(h).”

30. Chapter 11 of the Medicare Managed Care Manual states that “MA organizations are obligated to comply with other laws, specifically Federal laws and regulations designed to prevent or ameliorate fraud, waste, and abuse including, but not limited to: Applicable provisions of Federal criminal law; The False Claims Act (31 U.S.C. 3729 et seq.); The Anti-kickback statute (Section 1128B(b) of the Act); and HIPAA administrative simplification rules at 45 CFR Part 160, 162, and 164.”)

31. “Compliance with the AKS is clearly a condition of payment under Parts C and D of Medicare.” *U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 313 (3d Cir. 2011).

32. Based upon the bid, CMS agrees to pay the MAOs a monthly capitated payment for each member in the plan. Adjustments are made based upon the “risk profile” of the members. MAOs are paid more for members who are more costly.

33. MAOs submit “encounter data” to CMS that reflects the services provided to their members. MAOs with over 100,000 members are required to submit this data on at least a weekly basis. Large MAOs often submit the data more frequently than that due to the size of the data. The encounter data is an electronic record that contains detailed information for each medical service and item provided to an enrollee, and includes approximately 200 data elements. These elements include information on the patients, providers, and payers of services and items, as well as the dates of service and procedure codes. One element—“CLM02”—reflects the amount paid for items or services.

34. Each month MAOs are required to provide CMS their enrollment and payment data and request payment. They submit a certification states that “the MA Organization hereby requests payment under the contract, and in doing so, makes the following certifications concerning CMS payments to the MA Organization. . . . Based on best knowledge, information, and belief, all

information submitted to CMS in this report is accurate, complete, and truthful.”

35. “All contracts or written arrangements between MA organizations and first tier, downstream, and related entities must contain the following: . . . (iii) A provision requiring that any services or other activity performed by a first tier, downstream, and related entity in accordance with a contract are consistent and comply with the MA organization’s contractual obligations.” 42 C.F.R. § 422.504 (i).

36. A “first tier means any party that enters into a written arrangement, acceptable to CMS, with an MA organization or applicant to provide administrative services or health care services for a Medicare eligible individual under the MA program.” 42 C.F.R. § 422.2.

37. Part D of the Medicare Program offers prescription drug coverage to beneficiaries through use of private managed health companies referred to as “Part D Sponsors.” Part D Sponsors administer the program through the creation of drug formularies—a preferred list of drugs that may be reimbursed under the program. Part D sponsors reduce the cost of the program by negotiating rebates from drug manufacturers, which are then passed on to the Government and program beneficiaries. Part D sponsors submit a Prescription Drug Event (“PDE”) to CMS, which is a claim for payment for the sale of drugs under the plan.

38. Many insurance companies combine their Medicare Advantage plans with Part D plans to offer Medicare Advantage Prescription Drug plans.

3. Other Government-Funded Health Programs

39. In addition to Medicare, the federal government reimburses a portion of the cost of durable medical equipment and prescription drugs under several other federal healthcare programs, including, without limitation, programs administered by the Department of Defense (the “DOD”),

the Department of Veteran's Affairs (the "VA"), and the Office of Personnel Management (the "OPM").

40. The DOD administers TRICARE (formerly CHAMPUS), a health care program covering individuals and dependents affiliated with the armed forces. The VA administers its own health program, along with CHAMPVA (a shared cost program), covering families of veterans. OPM administers the Federal Employee Health Benefit Program, a health insurance program covering federal employees, retirees, and survivors.

41. Reimbursement for medical supplies under these programs may occur either through direct purchase of drugs later administered at government facilities or through coverage of medical supplies administered by other providers to individuals eligible for benefits under these programs.

4. Drug Formularies

42. Drug formularies are utilized by many different types of entities, including managed care organizations, pharmacy benefit management companies, State Medicaid plans, hospitals and long-term care facilities. Drug formularies specify which drugs are stocked, which ones are covered, and what the patients' cost-sharing obligations are.

43. Formularies play a critical role in controlling drug program costs because they incentivize patients to make efficient and economical choices when medically suitable alternatives exist. If a drug is on formulary, it will necessarily be covered when prescribed, subject to potential restrictions designed to address any individual patient needs.

44. Medicare requires that certain medications and durable medical equipment (such as diabetic test strips, nebulizers and wheelchairs) be covered under Part B. Medicare Part D plans usually do not cover drugs that are covered under Medicare Part B. Medicare Part B will typically

cover drugs that are administered at a hospital or doctor's office.

45. Managed Care plans such as Humana, Inc. commonly offer a limited drug formulary, obtaining significant discounts from one manufacturer by not offering a competing manufacturer's drugs or by offering the competing manufacturer's drugs with a high copayment.

46. Managed Care plans such as Humana, Inc. commonly require that drugs taken on an on-going basis be purchased from mail order pharmacies, which can offer significant discounts through large volume purchasing, while at the same time eliminating the added overhead costs of retail pharmacies.

V. DEFENDANTS' KICKBACKS AND FALSE CLAIMS

A. Roche's Illegal Kickback Scheme Resulted in False Claims Paid By the Government for Roche's Products

47. Relator discovered during her tenure at the Company that Roche had paid Humana for access to its Medicare Advantage formularies when it decided not to recover rebate overpayments it had learned Humana owed it under certain contracts to deliver Roche products to its members.

48. Humana provides health insurance plans nationwide, including Medicare Advantage and Part D insurance. Humana's three books of business consist of Medicare, Commercial, and "RightSource," a mail-order pharmacy, which primarily disbursed to members covered by government insurance programs. Roche's products were included in all three of Humana's books of business.

49. Humana's formularies included Roche Diabetes' Accu-Chek product line, which includes: (i) the Accu-Chek Spirit Insulin Pump; (ii) Accu-Chek test strips used to feed blood samples into a glucose testing meter; (iii) Accu-Chek meters to read the test strips; and (iv) lancets to make small punctures in the skin to draw blood samples. Roche's glucose strips, meters, and

lancets are collectively used by diabetics to manage their blood sugar.

50. On March 6, 2013, Humana notified Roche that its Medical Benefit Rebate Agreement for Humana's RightSource contract would be terminated in 90 days. Roche understood that, following such termination, Roche's products would no longer appear on Humana's RightSource formularies. This development was viewed within Roche as a significant blow to the company, particularly given that Roche had recently experienced other financial setbacks.

51. In May 2013, soon after Relator took over the Humana account from Roche National Accounts Manager Ernie Pasqualone, Relator discovered that Humana had not complied with the terms of its agreement with Roche. Under the contract, Humana was required to charge its members copays for non-formulary diagnostic products that were at least \$25 higher than their copays for Roche products that were on the formulary. Therefore, Roche had been paying Humana rebates that were not owed under the terms of Roche's contract with Humana.

52. Relator arranged a face-to-face meeting in Pittsburg, PA with Bethany Stein, who was responsible for Medicare Rebate Contracting Strategy at Humana, to discuss the overpayment on June 6, 2013. Upon being advised of the overpayment, Ms. Stein did not dispute its accuracy, but replied that such overpayments had been found in connection with several other similar contracts. Ms. Stein and Relator agreed at the conclusion of the meeting that it would be appropriate for Roche to quantify the amount of the overpayment.

53. Ms. Stein also indicated that Humana had been discussing within Roche whether the company's products should be removed from books of business other than RightSource as well. Relator understood that Humana was authorized to remove Roche's products from its formularies with just 90 days' notice.

54. On June 20, 2014, Relator spoke by telephone with Mr. Pasqualone and Ms. Stein

regarding the rebate calculations. Ms. Stein stated that due to the potentially large size of the reimbursement, Humana had decided to use an auditor to perform a more formal calculation.

55. Soon after the June 6 meeting, Roche's Finance Department determined that it would quantify the amount of the overpayment to Humana. Relator was advised at that time that the total amount of the overpayment was \$45 million.

56. Roche immediately recognized an opportunity to be placed back on Humana's formularies. General Manager Mark Gibley directed Vice-President of Finance David Barnes to prioritize Roche's continued relationship with Humana and do whatever it would take to preserve the relationship. Mr. Barnes, in turn, instructed Relator to emphasize Roche's continuation of the Humana contracts in its anticipated negotiations with Humana concerning the overpayment. Mr. Barnes also instructed Relator to report directly to himself about the negotiations, and not to speak with anyone else about them.

57. Despite Humana's initial stated preference that the parties engage a formal auditor, both parties subsequently agreed not to include an auditor in the negotiations. Mr. Dostal stated in a telephone call that Humana would not go down that route.

58. Internally, Roche prepared an analysis quantifying the value of the Accu-Chek product line's placement on Humana's Medicare Advantage and RightSource formularies. Roche's analysis was formalized in an Excel document.

59. On July 8, 2013, Kendra Moran, a member Roche's contract support team, sent Relator an email stating, "For your call with Humana today, you can present them with the amount of \$27.6m which includes \$2.4m of interest (5% compounded annually.)" Roche requested this amount from Humana because Roche did not want to jeopardize their relationship by presenting the larger \$45 million number Roche had previously calculated. Relator noted in an email that

“Humana requested the amount . . . for an internal meeting with William Flemming [*sic*].” At the time, William Fleming was Segment Vice President for Humana Inc. and President of Humana Pharmacy Solutions.

60. During the call with Ms. Stein and Mr. Pasqualone, Relator communicated the \$27.6 million figure to Ms. Stein. In response, Ms. Stein asked Relator and Mr. Pasqualone whether there was room for negotiation of the amount to be repaid by Humana. Ms. Stein added that she would prefer to have her company’s legal team attend their next phone call regarding the issue.

61. On July 9, Relator attended a conference call with Kim Ober and Holly McMasters to discuss the foregoing developments with Humana. Ms. Ober stated that she would conduct an analysis on the financial implications of the breach on Roche.

62. On July 10, 2013, Ms. Stein emailed Relator and Mr. Pasqualone stating that Ms. Stein “[j]ust had a mtg [*sic*] with senior leadership. . . . They would rather it be a business conversation and not involve legal for this first meeting. Can we do that?” She further stated that she would have Keith Dostal, Vice President of Supply Chain Strategies at Humana, and Mr. Fleming, among other Humana executives, attend the call on Friday, July 12, 2013.

63. On July 11, 2013, Mr. Barnes sent Ms. Stein an email attaching a letter formally requesting repayment of the rebates. Upon receipt of the request, Ms. Stein sent Relator an email saying, “This is pretty harsh. . . . Not reflective of our conversation today. Should I still expect what we discussed earlier?”

64. During the July 12, 2013 call, Mr. Dostal stated that he would authorize payment of no more than \$20 million. Over the course of the next several months, Roche and Humana negotiated a reduced sum to be returned in exchange for access to Humana’s RightSource book of

business, as well as continued access to the Medicare and Commercial formularies. Humana's return of Roche's rebate overpayments, and Roche's renewed access to Humana's formularies were expressly negotiated part of the same bargain.

65. Among the members of the Roche team participating in the negotiations were Mr. Barnes and Relator. The Humana team included Mr. Dostal, Ms. Stein, and Todd Hanley, Strategic Consultant—Trade Relations. Roche's team largely operated out of Indianapolis, Indiana.

66. These negotiations were held through e-mail communications and conference calls among Mr. Barnes, Mr. Dostal and other Humana personnel during this period, including Ms. Stein and Mr. Hanley.

67. Relator Derrick repeatedly expressed concerns that the resulting transaction would violate the AKS. Relator had helped create an instructive AKS video for past employment, so she was personally aware of the illegality of the negotiations.

68. In addition to raising concerns within the negotiation group, Relator discussed her concerns about the negotiations with Dan Majestic, Director of Channel Sales, and Lisa Rich-Milan, National Sales Director, Channel/Managed Markets. Upon information and belief, Mr. Majestic informed Mr. Barnes that Relator had raised concerns about the negotiations with him.

69. During the first week of December 2013, Roche signed a contract to regain access to Humana's formularies. Unlike Roche's prior contracts with Humana, the new contract excluded competing brand products from Humana's formularies. This formulary adjustment resulted in a substantially increased market share for Roche's products under the new Humana contract.

70. That same week, Humana paid Roche their reduced debt as agreed upon in the preceding negotiations. The final sum did not exceed \$11 million. Further, Roche's new contract with Humana provided that, if the performance under the contract was not satisfactory, Roche

could recover the money Humana had owed it but that Roche had refrained from collecting.

71. Roche's reduction of Humana's obligation to repay Roche in exchange for new and continued access to Humana's formularies violates the AKS's prohibition against providing and accepting remuneration for referral of medical items and services paid for by federal healthcare programs.

B. Humana Falsely Certified Compliance in Its Medicare Bids and Monthly Submissions to CMS

72. In 2013 and 2014, Humana bid on the Medicare Advantage program and participated in the program. In order to participate in the Medicare Advantage program, Humana would be required to sign a contract with CMS agreeing to "comply with— (1) Federal laws and regulations designed to prevent or ameliorate fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. 3729 et. seq.), and the anti-kickback statute (section 1128B(b) of the Act)." 42 C.F.R. § 422.504(h)."

73. In exchange for the debt forgiveness from Roche, Humana agreed to place Roche products on its RightSource and Medicare Advantage formularies. Humana provided Roche products with favorable treatment such that Humana's Medicare Advantage members would purchase Roche products.

74. In order to receive Government payment, Humana submitted encounter data and monthly reports and certifications to the Government. The sale of Roche products to Humana's Medicare Advantage members would be reflected in Humana's submission of encounter data and monthly reports to CMS.

75. In the monthly submissions, Humana would be required to certify that "all information submitted to CMS in this report is accurate, complete, and truthful."

76. By making the regular submissions that were required in order for Humana to receive CMS payments, Humana impliedly certified that it was complying with the contract requirements, including compliance with the FCA and the AKS.

77. As a result of making the submissions to the Government, Humana was paid a capitated rate for its members.

C. Roche Retaliated Against Relator for Raising Concerns About Roche's Unlawful Conduct

78. Relator's discovery of overpayments to Humana that Roche had long neglected was widely praised by senior employees within the company. Mr. Gibley suggested to Relator that she could expect to receive an end of the year recognition award for her work.

79. However, Relator eventually became concerned about Roche's planned response to her discovery of the overpayment. In particular, Relator repeatedly raised concerns with her contract support team, Kim Ober and Ms. Moran, about the lawfulness of Roche's seeking recovery of only a portion of Humana's debt to Roche in exchange for a new, two-year agreement. Ultimately, Relator was told that the decision had been made by a member of senior leadership, Mr. Gibley.

80. In October 2013, Relator participated in a call with a client that had required her to provide the client with certain pricing information. Relator had on earlier occasions told her manager, Dan Majestic, that the prices he had suggested for clients were not competitive.

81. Repeatedly over the course of approximately one week, Relator asked Mr. Majestic to provide her with competitive pricing for the client's contract. Mr. Majestic finally sent Relator an email attaching the information to be forwarded to the client only minutes in advance of the call. Nothing in Mr. Majestic's email stated that the accompanying information was confidential or had not been approved internally.

82. Relator forwarded the pricing information to the client immediately, so that the client would receive it in advance of the call. Following receipt of the pricing information, the client expressed disapproval, explaining that the prices were not competitive.

83. Over the next several weeks, Mr. Majestic repeatedly demanded that Relator identify the information she had forwarded to the client. Relator responded on several occasions that she could not locate the email that had attached the information, due to a computer malfunction, but offered to ask the client to send her a copy of the email. Relator also sent Mr. Majestic an email reflecting the same response.

84. In mid-November 2013, Mr. Majestic advised Relator that the prices he had sent her in advance of the call had not been approved by the Company for transmission to the client. Relator was unable at that time to understand why Mr. Majestic would send her prices a few minutes in advance of a client call when they had not been approved for transmission.

85. In early December 2013, Mr. Majestic asked to join one of Relator's upcoming customer meetings that was to take place on December 8 in Louisville, Kentucky. The meeting would be the second of its kind that he would attend within a span of two months. Because Mr. Majestic's past practice had been to attend only one or two customer meetings per year, his attendance of two such meetings within this shorter interval was highly unusual.

86. During the December 8 customer meeting, the customer, who happened to be a representative of Humana, highly complimented Relator for her diligent work on the customer's contract.

87. After the customer meeting, Mr. Majestic told Relator that she was to meet with a Roche human resources representative, Ms. Teresa Stroble, at a hotel near the Louisville airport. Mr. Majestic provided Relator with a handwritten note indicating the address of the hotel.

88. At the meeting, Ms. Stroble advised Relator that she was to be terminated from her employment with Roche, resulting from her role in the events surrounding the October 2013 client call. In response to Relator's question whether there was any other reason for her termination, Ms. Stroble stated that Relator's role in the events surrounding the October 2013 client call was the sole reason.

89. Relator advised Ms. Stroble that she had sent Mr. Majestic an email offering to ask the client to forward her Relator's prior email, to which she had attached the pricing information the client had disapproved of. Ms. Stroble responded she had not been made aware of this email and asked Relator to leave the room while she spoke with Mr. Majestic.

90. Upon Relator's return, Ms. Stroble advised that Relator's offer to retrieve the email from the client did not change the Company's position and that Relator would be terminated effective December 10, 2013.

91. Relator did not receive a severance or compensation for her unused vacation time upon her termination from Roche.

VI. CAUSES OF ACTION

COUNT I

Presenting False Claims (False Claims Act, 31 U.S.C. § 3729(a)(1)(A))

92. Relator realleges and incorporates by reference the allegations in the previous paragraphs of this Second Amended Complaint.

93. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729-3732.

94. By virtue of the acts described above, Defendants knowingly submitted, caused to be submitted and continue to submit and to cause to be submitted false or fraudulent claims for

payment by the United States, by knowingly or recklessly submitting claims to Federal healthcare programs services tainted by Defendants' payment and receipt of remuneration in exchange for access to Humana's formularies, in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b).

95. The United States, unaware of Defendants' kickbacks, paid false claims when it paid for Roche's products on Humana's formularies.

96. The falsity of the claims presented by Defendants was material, as the falsity concealed material violations of the FCA and the AKS that would have justified denial of the claims in their entirety. Had Federal healthcare officials known of Defendants' kickbacks, the Government would not have paid Defendants for the goods and services furnished as a result of the kickbacks.

97. Defendants' knowing presentation of false claims for payment by the United States has violated 31 U.S.C. § 3729(a)(1)(A) and has damaged, and continues to damage, the United States in an amount to be determined at trial.

COUNT II
Making False Statements Material to a False or Fraudulent Claim
(False Claims Act, 31 U.S.C. §3729(a)(1)(B))

98. Relator re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

99. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729-3732.

100. By virtue of the acts described above, Defendants knowingly submitted, caused to be submitted and continue to submit and to cause to be submitted false records and statements material to false or fraudulent claims for payment by the United States.

101. Defendants' false statements material to false or fraudulent claims for payment by the United States have violated 31 U.S.C. § 3729(a)(1)(B) and have thereby damaged and continue to damage the United States Government by its actions in an amount to be determined at trial.

COUNT III
Conspiracy to Violate the False Claims Act
31 U.S.C. § 3729 (a)(1)(C)

102. Relator realleges and reincorporates all the preceding paragraphs of the Complaint as if fully set forth herein.

103. By virtue of the acts described above, Defendants violated the False Claims Act by conspiring to knowingly and willfully conspiring to cause the submission of false claims to obtain payments from Medicaid and Medicare.

104. It was a part of this conspiracy that Defendants knowingly and willfully submitted false claims to Medicaid and Medicare for ineligible medical services.

105. As a result of these false claims, the United States has been damaged and continues to be damaged in an amount to be determined at trial.

COUNT IV
Retaliation for Protected Conduct
(False Claims Act, 31 U.S.C. § 3730(h))

106. Relator realleges and reincorporates all the preceding paragraphs of the Complaint as if fully set forth herein.

107. Roche's harassment and ultimate termination of Relator's employment was made in retaliation for her questioning of the lawfulness of Defendants' conduct involving its efforts to gain access to Humana's formularies. Thus, Defendants' harassment and termination of Relator violate 31 U.S.C.A. § 3730(h).

108. Relator has been damaged by Defendants' unlawful actions as described above.

Hence, under § 3730(h), Relator is entitled to reinstatement, twice the amount of back pay she has failed to receive as the result of her termination, interest, emotional distress damages, attorney's fees, litigation costs, and other special damages.

VII. PRAYER FOR RELIEF

WHEREFORE, Relator prays for judgment against Defendants as follows:

A. An order that Defendants cease and desist from violating the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b);

B. Judgment against Defendants in an amount equal to three times the damages the United States has sustained because of Defendants' fraud, plus a civil penalty of \$11,000 for each claim submitted in violation of the False Claims Act, under 31 U.S.C. § 3729(a);

C. An award to Relator of the maximum share of money recovered from Defendants by, or on behalf of, the United States, under 31 U.S.C. § 3730(d)(2);

D. An award to Relator of "reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys' fees and costs," under 31 U.S.C. § 3730(d)(1);

E. An award to Relator of reinstatement, twice the amount of back pay she has failed to receive as the result of her termination, interest, emotional distress damages, attorney's fees, litigation costs, and other special damages; and

F. Such other relief as the Court deems just and proper.

VIII. DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands a trial by jury.

Filed this 30th day of June

Respectfully submitted,

/s/ Jamie Franklin

Jamie Franklin

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